



UNITED STATES PATENT AND TRADEMARK OFFICE

FEB 15 2001

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UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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James J. Sales
ELI LILLY AND COMPANY
Patent Division/jjs Lilly Corporate Center
INDIANAPOLIS IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

#19

Dear Mr. Sales:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: EVISTA
FDA Docket No.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company
Request for Patent Term Extension
U.S. Patent No. 4,418,068

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: ORDER GRANTING
: INTERIM EXTENSION

Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156 on January 20, 1998. The original term of the patent is due to expire on April 3, 2001. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA" which was approved by the Food and Drug Administration (FDA) for commercial marketing or use on December 9, 1997. An extension of 1,103 days is requested.

The initial USPTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by FDA. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the original expiration date of the patent, until April 3, 2002.

JAN 30 2001
Date

Nicholas P. Godici
Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office